Nos. 09-993, 09-1039, and 09-1501

In The
Supreme Court of the United States

Pliva, Inc., et al., *Petitioners*,
v.
Gladys Mensing, *Respondent*.

Actavis Elizabeth LLC, *Petitioner*,
v.
Gladys Mensing, *Respondent*.

Actavis, Inc., *Petitioner*,
v.
Julie Demahy, *Respondent*.

On Writs of Certiorari to the United States Courts of Appeals for the Fifth and Eighth Circuits

BRIEF OF PUBLIC CITIZEN AND AARP AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae Public Citizen and AARP are national non-profit organizations that represent the interests of consumers, including many who regularly use generic prescription drugs. Public Citizen is a membership organization devoted to research, advocacy, and education on a wide range of public-health and consumer-safety issues, including safe, effective, and affordable health care. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and petitioned the Food and Drug Administration (FDA) to act to reduce safety risks. Public Citizen has a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety laws, and its lawyers have represented parties in many significant federal preemption cases, including *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008) (Mem.), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

AARP, an organization for persons 50 years old and over, works to foster the health and economic security of people as they age. To that end, AARP supports efforts at state and national levels to ensure access to safe and effective health care services and products. AARP is concerned about the safety of prescription drugs because older people disproportionately use them. AARP supports

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[1]No counsel for a party authored this brief in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amici curiae* made any monetary contribution to this brief's preparation or submission. The parties' letters of consent to the filing of amicus briefs have been filed with the Clerk.

laws and public policies that protect its members' rights and preserve the availability of legal redress when its members are harmed in the marketplace.

Amici are filing this brief because this case has the potential to broadly impact the safety of prescription drugs. As this Court noted in *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009), "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." They also "serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.* Generic drugs account for approximately 70 percent of prescriptions filled in the United States. Barring failure-to-warn claims against generic drug manufacturers would decrease the companies' incentive to disclose safety risks promptly, reduce injured consumers' motivation to come forward with information, and deny consumers redress for the injuries they suffer when the drugs they take lack appropriate warnings.

Amici recognize that generic drugs are important in providing affordable drugs to consumers, including the elderly. Indeed, because of the benefits to consumers of having access to generic drugs, representatives of both Public Citizen and AARP testified in support of abbreviated procedures for approval of generic drugs during hearings on the Hatch-Waxman Act when it was being considered by Congress. As AARP testified: "We think that this little bill has the potential for being the biggest consumer interest piece of legislation in this decade." *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 98th Cong.

59 (July 25, 1983). *Amici* are concerned, however, that, through preemption, a statute intended to provide consumers with increased access to *safe* generic drugs will be used to deny consumers necessary protections against *unsafe* ones.

SUMMARY OF ARGUMENT

State-law failure-to-warn claims further the purposes of the Hatch-Waxman Act. In enacting Hatch-Waxman, Congress sought to make generic drugs available to American consumers, but not at the expense of drug safety. The goal was safe, affordable drugs. State-law claims against generic drug manufacturers create incentives for those companies to ensure that their drugs are safe and contain appropriate warnings, and they provide relief to consumers who are injured by generic drug companies' failure to meet their duties of care. In contrast, holding state-law claims against generic drug manufacturers preempted would effectively punish consumers for choosing generic drugs over their name-brand alternatives. And it would send the message that generic drugs are less trustworthy than name-brand drugs—contrary to Congress's goal of reducing drug prices through competition by generic drugs.

That generic drugs do not enter the market until after the patent on the name-brand drug has expired, and therefore not until years after the name-brand drug has been on the market, does not eliminate the need for generic drug manufacturers to be alert to evidence of undisclosed risks and the need for additional warnings. Whether or not drugs are safe and what sorts of warnings are necessary are often not known until drugs have been

on the market for years. Particularly because generic drugs have a large share of the market, it is important that generic drug manufacturers have incentives to promptly and appropriately disclose safety risks.

The extent to which generic drug manufacturers have authority to alter their labels is disputed by the parties here. But it is uncontested that, at the least, they are free to propose new warnings to the Food and Drug Administration (FDA) and to ask the FDA to send "Dear Doctor" letters alerting health-care professionals to newly discovered risks. Because generic drug manufacturers can take measures to ensure that their products have adequate warnings—measures not only permitted but encouraged by the federal regulatory scheme—state-law failure-to-warn claims are not preempted.

ARGUMENT

I. The Hatch-Waxman Act Does Not Sacrifice Safety to Competition.

State-law claims against generic drug companies for failure to fulfill their duty to warn consumers of their products' risks are consistent with the goals of the Hatch-Waxman Act. *See Drug Price Competition and Patent Term Restoration Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Congress passed Hatch-Waxman in 1984 to make low-cost generic drugs more available to the public. *See* H.R. Rep. No. 98-857, pt. 1, at 14 (1984). It estimated that approximately 150 off-patent drugs first approved after 1962 had no generic equivalents and that making generic versions more easily available "would save American consumers $920 million over the [following] 12 years." *Id.* at 17.

Congress sought to achieve the goal of making low-cost drugs available to the public by reducing generic drug companies' barriers to enter the market. To this end, and out of recognition that generic drug companies need not duplicate previously conducted tests to demonstrate that their drugs are safe and effective enough to be approved, the Hatch-Waxman Act releases generic drug manufacturers from the obligation to submit the clinical study results needed to support a new drug application (NDA). Instead, a generic drug manufacturer may submit an abbreviated new drug application (ANDA) containing information showing that the generic drug's conditions of use, active ingredients, route of administration, dosage form, labeling, and strength are the same as those of the corresponding name-brand drug, and that the generic is bioequivalent to the name-brand drug. Pub. L. No. 98-417, § 101, *codified at* 21 U.S.C. § 355(j)(2)(A)(i)-(v).

Although, Hatch-Waxman sought to quickly "make available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14, it did not pursue that aim at all costs. In particular, Congress did not abandon the requirement that drugs be safe. "There is no indication that when Congress passed the Hatch-Waxman Amendments it intended the goal of delivering low cost generic drugs to supplant the FDCA's overall goal of providing consumers with safe and effective drugs." *Gaeta v. Perrigo Pharms. Co.*, __ F.3d __, 2011 WL 198420, at *11 (9th Cir. Jan. 24, 2011). Rather, the policy objective was to "get[] *safe and effective* generic substitutes on the market as quickly as possible." H.R. Rep. No. 98-857, pt. 2, at 9 (emphasis added). Indeed, the law's provisions demonstrate a continued focus on maintaining drug safety and

effectiveness. *See, e.g.*, Pub. L. No. 98-417, § 101, *codified at* 21 U.S.C. § 355(j)(2)(C)(ii) (providing that the Secretary can deny a petition to file an ANDA for a generic drug with a different active ingredient than an approved drug if the drug "may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted" in the ANDA). In short, although the Hatch-Waxman Act's goal was to get low-cost generic drugs to consumers, it did not exchange safety for reduced prices. The Hatch-Waxman Act was intended to be a win-win situation in which generic drugs would be approved more quickly with no decrease in safety or effectiveness.

In crafting a law to increase drug-price competition, Congress focused on market entry, not on post-entry regulation. The Hatch-Waxman Act does not detail generic drug manufacturers' duties after the drug is approved or absolve them of responsibility for the safety of the drugs they manufacture. Indeed, at hearings on the legislation, representatives of the generic drug industry recognized their continuing responsibility for their products after approval. For example, Kenneth N. Larsen, the chairman of the Generic Pharmaceutical Industry Association, stated that generic drug companies were "sensitive to the importance of looking at adverse reactions." *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 98th Cong. 45 (July 25, 1983). "The generic manufacturers of today will respond to those needs," he continued. "If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need." *Id.* Larsen repeated the assurance of drug company responsibility in response to a

question from Representative Waxman about whether the NDA holders were better able to correct problems than generic companies. After acknowledging that the companies that performed the research would have more intimate knowledge of the drug, Larsen assured Mr. Waxman:

> I can state for my company as well as I think I can state for the other generic companies that produce these products, that we will do and provide whatever is required to be performed to meet the regulatory requirement to provide for the safety and well-being of those that are using the drug, this is our role and responsibility. This is an obligation to be in this business.

Id. at 47-48.

Similarly, Bill Haddad, executive officer and president of the Generic Pharmaceutical Industry Association, called concerns about whether generic drug companies would adequately report adverse events a "red herring." *Id.* at 50. "There seems to be a misconception about [] generic drug companies," he noted. "We also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reactions." *Id.* at 50-51. And in response to a question about whether generic drug companies were responsible for reporting adverse event reactions to the FDA, Milton A. Bass, General Counsel to the National Association of Pharmaceutical Manufacturers, which represented

generic drug companies, responded: "Not only yes, Mr. Chairman, but they should be." *Id.* at 47.

In discussing the importance of the Hatch-Waxman Act during the legislative process, members of Congress emphasized their intent to benefit American consumers, particularly older Americans. "Most importantly," Representative Skelton explained in discussing the bill on the House floor, "making generic drugs more available offers some relief to the millions of older Americans whose budgets are strained because medicare does not cover the cost of outpatient drugs. . . . Giving seniors the option of purchasing lower-priced generic drugs is imperative." 130 Cong. Rec. 24437 (Sept. 6, 1984). "Everyone in this country will benefit by enactment of this legislation," Representative Minish agreed, "but I feel it is particularly important that our senior citizens who fill more prescriptions than other segments of our population, can save money on their medical bills." *Id.* at 24456. "This is important legislation," Representative Fish noted. "[I]t is important to the consumer, especially the elderly." *Id.* at 24428.

This Court recently noted that, in enacting the FDCA and its amendments, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers" and "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Wyeth*, 129 S. Ct. at 1199-2000. Congress gave no indication that, in seeking to benefit American consumers through lower drug prices, it intended to decrease generic drug companies' incentives to ensure that their drugs are safe, effective, and contain

adequate warnings, or to deny consumers the ability to seek compensation for injuries caused by drugs with inadequate warnings. Under petitioners' position, however, generic drug manufacturers would have no incentive to ensure that their drugs contain adequate warnings, because they could not be held accountable if their drugs did not.

Moreover, consumers would have no remedies for injuries incurred as a result of inadequate warnings. Many courts, including the Eighth Circuit below, have held as a matter of state law that consumers injured by inadequately labeled generic drugs have no claims against the name-brand manufacturer, because they were not injured by that manufacturer's drug. *See, e.g.*, JA 418-21; *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616 (E.D. Tex. 2010); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643 (W.D.N.C. 2010); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351 (N.D. Ga. 2008); *but see Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). Yet, according to petitioners, injured consumers should also be denied an opportunity to seek compensation from the company that manufactured the drug that they did take. As the Fifth Circuit noted below, however, it would be "bizarre" to hold that "Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while under *Levine*, that same plaintiff would have a state-law claim had she only demanded a name brand drug instead." JA 563.

Because Hatch-Waxman's goal was to get *safe* generic drugs into consumers' hands, state-law failure-to-warn claims against generic drug companies further the Act's

purposes, helping to ensure that the companies take reasonable steps to ensure that their drugs contain proper warnings and, therefore, can be used safely. In contrast, denying injured consumers of generic drugs compensation for their injuries would be contrary to the purposes of the Act. In enacting Hatch-Waxman, Congress recognized the importance of generic drugs and the savings that they bring to the public. If generic drug manufacturers are immune from liability, however, injured consumers would essentially be punished for using generic rather than name-brand drugs. Moreover, already, consumers often incorrectly believe that generic drugs are less safe than their name-brand counterparts. *See, e.g.*, FDA, *Facts and Myths About Generic Drugs*, www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (noting the "myths" that "[p]eople who are switched to a generic drug are risking treatment failure," that "[g]eneric drugs cost less because they are inferior to brand name drugs," and that "[b]rand name drugs are safer than generic drugs"). Sending the message that generic drug companies are not accountable for the safety of their products would only further that belief.

II. Risks Associated With a Particular Drug Often Do Not Become Known Until Long After the Drug Has Been Approved.

Generic drugs do not enter the market until after the name-brand drug has been approved and its patent has expired. But the length of time between the initial approval of the name-brand drug and the approval of the generic drug does not ensure the drug's safety or that its label contains adequate warnings. Because risks often do

not become apparent until long after a drug has been approved by the FDA, it is vital that all drug manufacturers—including generic drug manufacturers—have incentives to respond to safety risks as they become known.

The safety of new drugs "cannot be known with certainty until a drug has been on the market for many years." Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 JAMA 2215 (2002). A study in the Journal of the American Medical Association on the frequency and timing of the discovery of adverse drug reactions (ADRs) requiring black-box warnings or drug withdrawal concluded that "only half of newly discovered serious ADRs are detected and documented in the *Physicians' Desk Reference* within 7 years after drug approval." *Id.* at 2218. The study noted that Pemoline, a central nervous system stimulant, received its first *Physicians' Desk Reference* black-box warning 22.9 years after it was approved; Danazol, a drug for infertility, received its first black-box warning 15.5 years after approval; and Disopyramide Phosphate, an antiarrhythmic, added its first black-box warning 19.3 years after approval. *Id.* at 2217. In November 2010, the FDA announced that the popular painkiller Propoxyphene (known by the brand names Darvon and Darvocet), which was first approved in 1957, would be removed from the market because of cardiac risks. *See* FDA, *Propoxyphene-Containing Products*, www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm233800.htm. In 2007, 21.3 million prescriptions had been filled for the generic combination of propoxyphene and

acetaminophen, making it one of the most-prescribed generic drugs in the United States. *See* Sidney M. Wolfe, M.D., *Testimony on Propoxyphene (Darvon) Before FDA's Anesthetic, Analgesic and Rheumatologic Drugs and Drug Safety and Risk Management Advisory Committees* (Jan. 30, 2009), *available at* www.citizen.org/Page.aspx?pid=537.

The long history of a black-box warning recently placed on fluoroquinolone antibiotics such as Cipro demonstrates how warnings can change over time, including after both name-brand and generic drugs are approved. The first floroquinolone drug was approved by the FDA in 1986. Over the following years there were reports of tendon inflammation and rupture associated with fluoroquinolones. Based on these reports, in 1996, *amicus curiae* Public Citizen successfully petitioned the FDA to place a warning regarding the risk of tendinopathy and tendon injury on the package insert of fluoroquinolone drugs. *See* Public Citizen, *Petition to Require a Warning on All Fluoroquinolone Antibiotics* (Aug. 1, 1996), *available at* www.citizen.org/hrg1399. The warning was in plain type alongside a list of other risks. Thereafter, however, fluoroquinolone-induced tendon injures continued to occur at an alarming rate. Thus, in 2008, FDA notified manufacturers of the need to add a black-box warning to their labels. *See* FDA, *Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs* (July 8, 2008), *available at* www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm. This black-box warning was added more than 20 years after the approval of the

first name-brand fluoroquinolone drug, and years after generic versions came on the market.

Because new knowledge can require new warnings, drug manufacturers must take reasonable steps to ensure that their drugs are adequately labeled. As the Court noted in *Wyeth*, "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." 129 S. Ct. at 1202; *see also, e.g., id.* at 1202 n.11 (citing studies showing that FDA resources are inadequate for it to meet its regulatory responsibilities). And although the Food and Drug Administration Amendments Act of 2007 gave the FDA additional resources for drug safety and new authority to compel manufacturers to make labeling changes, *see* Pub. L. No. 110-85, 121 Stat. 823 (2007), "the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does." 153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (Statement of Sen. Kennedy).

Generic drug companies are often in the best position to discover, assess, and take early action to address risks that come to light after the name-brand drug's period of patent exclusivity has ended because, once generic drugs are available, they often have the majority market share for the drug. Overall, approximately 70 percent of prescriptions are filled with generic drugs. *See, e.g.*, FDA, *Facts and Myths About Generic Drugs*. Generic drug manufacturers are already subject to the same

requirements as name-brand drugs regarding the "reporting and recordkeeping of adverse drug experiences." 21 C.F.R. § 314.98(a). They should not be immune from liability under state law if they fail to take reasonable steps to ensure that consumers are properly warned about risks from their products.

III. Generic Drug Manufacturers Can Act to Warn Consumers About the Dangers of Their Drugs.

Respondents' state-law claims allege that petitioners failed to take reasonable care to adequately warn patients of the risks associated with their products. The parties disagree about the scope of generic manufacturers' authority to alter their labels, but they agree that generic manufacturers can take some actions, such as asking the FDA to require a labeling change or to send out a "Dear Doctor" letter. *See* Pliva Br. 48. Indeed, the FDA has advised that, "[a]fter approval of an ANDA, if an ANDA holder believes that new safety information should be added [to a product's labeling], it should provide adequate supporting information to FDA." 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992). State-law claims seeking to hold a generic drug manufacturer accountable for failing to take action that a reasonable manufacturer would take to warn patients of dangers associated with its product—actions that are allowed, even encouraged, by the federal regulatory scheme—are wholly consistent with the goals of and duties imposed by that scheme.

Petitioners note that even if generic manufacturers asked for a warning or a Dear Doctor letter, the FDA might say no. To be sure, on the merits, petitioners may explain the restrictions and obligations of the federal

regulatory scheme and show their compliance with that scheme in support of their arguments that they took reasonable care to warn patients about the risks of metoclopramide. The law of every state allows such evidence and, in some states, requires that it be given substantial weight. *See, e.g., Restatement (Third) of Torts: Prod. Liab.* § 4; 63B Am. Jur. 2d *Prods. Liab.* § 1922 ("As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case."). In this way, the federal regulatory scheme can play an important role in litigating state-law failure-to-warn claims against drug manufacturers.

But the issue here is preemption. Petitioners argue that the regulatory scheme must be preemptive because litigating the case on the merits may require speculation about how the FDA would have responded to manufacturers' efforts to revise the labeling. *See* Pliva Br. 49. Name-brand manufacturers, however, also must seek FDA approval for labeling changes. Yet, in *Wyeth*, the Court held that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." 129 S. Ct. at 1198; *see also id.* (noting that the manufacturer "offered no such evidence"). By declining to hold failure-to-warn claims preempted, while recognizing that drug manufacturers might submit evidence of whether the FDA would have approved a label change, the Court recognized that state-law claims are not preempted whenever they might involve "speculation about what a federal agency would have done in hypothetical proceedings." Pliva Br. 53.

Petitioners attempt to distinguish *Wyeth* on the ground that name-brand manufacturers can change labeling under the "changes being effected" (CBE) process, which allows manufacturers to add or strengthen a warning without prior approval from the FDA, 21 C.F.R. § 314.70(c)(6)(iii)(A)), and that, therefore, "the brand manufacturer's new warnings could have reached consumers without FDA action." Pliva Br. 53. Even assuming that the FDA does not allow CBE changes for generic drugs, however, petitioners are wrong to portray the CBE process as giving manufacturers the ability to make labeling changes without FDA involvement. The CBE process simply allows the drug manufacturer to make the change while the request for permission to revise the labeling is pending, instead of requiring the drug manufacturer to obtain advance approval. *See* 21 C.F.R. § 314.70(c)(6). Thus, even in cases in which changes are made through the CBE process, the FDA may reject the request for a change, just as it might reject a change suggested by a generic drug manufacturer. *Id.* § 314.70(c)(7). Yet *Wyeth* does not hold that claims are preempted because the FDA *might* reject a change made under the CBE process; it concludes that claims are not preempted absent clear evidence that the FDA would not have approved a labeling change. Accordingly, petitioners' "speculation" objection is inconsistent with *Wyeth*.

Citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), petitioners also argue that state-law claims based on manufacturers' failure to take actions such as alerting the FDA to a newly discovered safety risk would "impose extraordinary burdens on the Agency" by "draw[ing] [it] into nationwide litigation." *Id.* at 55.

Notably, the FDA appears not to share petitioners' concerns. Although the United States stated in its petition-stage brief that "the court of appeals appeared to anticipate that the parties could litigate on remand the question of what action FDA would have taken in response to a hypothetical warning proposal from petitioners," it concluded that state-law failure-to-warn claims are not categorically preempted and recommended denying the petition. Br. of the U.S. as *Amicus Curiae* at 10, 20. And although petitioners imply that FDA employees will be forced to spend large amounts of time testifying, Pliva Br. 56-58, FDA regulations provide that employees may not "give any testimony before any tribunal pertaining to any function" of the FDA, "except as authorized by the Commissioner of Food and Drugs." 21 C.F.R. § 20.1; *see generally United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

Petitioners also contend that allowing claims based on manufacturers' failure to take actions such as asking the FDA for a label change should be preempted because they would cause generic drug companies to "inundate FDA with a deluge of submissions" that it "neither wants nor needs." Pliva Br. 30 (quoting *Buckman*, 531 U.S. at 351). But information about safety risks is information that the FDA *does* want and need. Indeed, the FDA has instructed manufacturers that "if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA." 57 Fed. Reg. at 17961. And petitioners' threat that they and other manufacturers will send "meritless" labeling-change requests to the FDA, Pliva Br. 60, is disingenuous. Generic drug companies are unlikely to ask the FDA to

add unnecessary warnings for fear that the FDA might comply with their requests. Moreover, the argument that allowing claims to proceed would cause drug companies to inundate the FDA with proposed labeling changes was made, and implicitly rejected, in *Wyeth*. *See* Br. for PhRMA and BIO as *Amici Curiae* Supporting Pet. at 36-38, in *Wyeth v. Levine*, No. 06-1249.

In any event, the question in determining preemption is not whether manufacturers' efforts to comply with state-law duties might lead to additional regulatory submissions. Rather, the question is whether the state-law claims and the regulatory scheme conflict. Here, there is no such conflict. If a generic drug manufacturer does not take the steps allowed by the regulatory scheme to provide adequate warnings, it should not be permitted to hide behind that scheme to avoid accountability for its actions.

CONCLUSION

The judgments below should be affirmed.

Respectfully submitted,

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